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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,429	03/14/2006	Alessio Moriconi	4342-0116PUS1	6234
2292 7590 08/20/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER NOLAN, JASON MICHAEL				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
08/20/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/541,429

**Applicant(s)**

MORICONI ET AL.

**Examiner**

JASON NOLAN

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-12 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 10 and 12 is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 11 and 16 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on June 11, 2009 has been entered. As filed, Claims 1, 3-12, & 16 are pending in the instant application; of which, Claims 1, 7, 8, 11, 12, & 16 are currently amended. Claims 2, 13-15, & 17 are cancelled.

### ***Response to Amendment***

Applicant's amendments with respect to Claims 1, 7, 8, 11, 12, & 16 have been fully considered and are entered. The 102 prior art rejection of Claims 8 & 12 over US 3,833,608 has been withdrawn per amendment. The 112 indefinite rejection of Claims 1 & 3-7 has been withdrawn per amendment. The objection to Claims 1, 9-11, & 15-17 are withdrawn.

### ***Claim Rejections - 35 USC § 102***

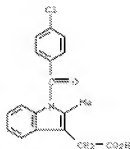
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

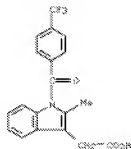
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, & 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,629,284. The '284 patent discloses indomethacin derivatives which are shown to be anti-inflammatory (*see in vivo* test results in column 12). The diseases claimed in the instant application are inflammatory disorders, and thus fall within the scope of the prior art. Specifically, the patent discloses Example 76, which is the same compound as the instant compound 16, shown on page 34 of the specification. Example 76 and other compounds found within the '284 patent, which fall within the scope of instant formula (I), are shown below:

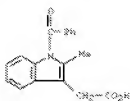
8N 1,649,012-8



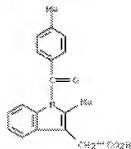
8N 1,649,012-83-5



8N 1,649,012-86-2

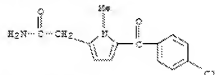


8N 1,649,012-83-5

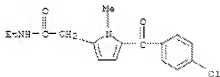


Claims 1 & 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,752,826. The '826 patent discloses pyrrole derivatives which are shown to be anti-inflammatory (*see in vivo* test results in column 10). The diseases claimed in the instant application are inflammatory disorders, and thus fall within the scope of the prior art. Specifically, the patent discloses the following amides that anticipate formula (I) wherein A = pyrrole; Y-R' = NH-(H, alkyl, OH,  $-(CH_2)_n-NR_aR_b$  and  $R_a, R_b = Et$ ), Hy = methyl; and R = substituted benzoyl:

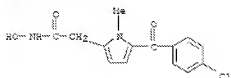
RN 26235-67-6



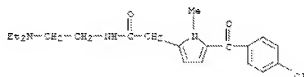
RN 26235-68-7



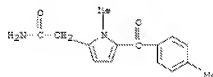
RN 33365-24-3



RN 33365-25-4



RN 33365-61-6



The first compound, RN 26235-67-6, corresponds to the instant compound 38, shown on page 36 of the instant specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention: the term “more preferably” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the invention. See MPEP § 2173.05(d).

Claims 11 & 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims must, under modern claim practice, stand alone to define an invention, *Ex parte* Fressola, 27 USPQ 2d 1608 (1993). The instant claim does not provide a structure (or chemical name) for formula (Ia) and one must refer back to the specification to define the claimed invention.

***Claim Objections***

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Said claim contains compounds that do not fall within the scope of formula (I) in Claim 1, the claim from which Claim 7 depends.

Claim 1 requires that the "R" variable be substituted on the "A" ring either at the 3-position or 4-position with respect to labels 1 and 2 shown in the figure for formula (I). The compounds in Claim 7 are shown in Table 1 of the specification on pages 33-36. Compound 31, for instance, has a substituted benzoyl at position 3, which is within the scope of formula (I); however, there is a methoxy functional group in the 4-position on the indole (Note: the 4-position of the indole is not the same as the 4-position designated by the claim language). The ring "A" only allows for one substituent, "R", and for this reason, compound 31 fails to further limit the base claim.

Claim 1 (Hy, Rd) and Claim 8 (Rd) are objected to because of the following informalities: the variables "C<sub>1</sub>-C<sub>6</sub>-alkenyl" should be "C<sub>2</sub>-C<sub>6</sub>-alkenyl" since a double bond requires at least two carbon atoms. Appropriate correction is required.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 7,291,644 and 7,135,495 are relevant to the instant application because the patents disclose anti-inflammatory compounds (*see* Table 1 in column 10 of the '644 patent) that fall within the scope of instant formula (I).

Claims 9, 10, & 12 are allowed.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan whose telephone number is (571) 272-4356 and e-mail is [Jason.Nolan@uspto.gov](mailto:Jason.Nolan@uspto.gov). The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571) 272-0699. The USPTO fax number for applications is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, (either Private PAIR or Public PAIR). Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. For questions on Private PAIR system, contact the Electronic Business Center at (866) 217-9197.

/Jason M. Nolan/

Examiner, Art Unit 1626\

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626